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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,493	07/11/2003	Luz Montesclaros	5063 US	5407

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EXAMINER	
SCHNIZER, RICHARD A	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,493	MONTESCLAROS ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 11 July 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 3/8/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An information disclosure statement was received and entered on 3/8/05.

Claims 1-31 are pending and under consideration in this Office Action.

Claim Objections

Claim 12 is objected to because "guanidium" is misspelled. Substitution of --guanidinium-- is suggested.

Claim 13 is objected to because "guanine" is misspelled. In view of the specification as a whole, the fact that the claim is referring to chaotropic agents, and the fact that the claim abbreviates guanine hydrochloride as "GuHCl (which is defined as "guanidine hydrochloride" in the specification and in claim 6), it seems clear that Applicant meant to refer to guanidine hydrochloride and not guanine hydrochloride. See e.g. the specification at paragraph 35 at page 17, and claim 6, line 4. The specification as filed does not refer to "guanine" hydrochloride except in claim 13.

Claim 14 is objected to because it is ungrammatical. Insertion of --to-- immediately after the last instance of "phase" is suggested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 16, and 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4, 16, and 31 contain several the trademark/trade names e.g. LDAO™, CHAPS™, CHAPSO™, EMPIGEN™, and others. In some cases the trademark/trade names are shown parenthetically after a chemical name, in other cases only the trademark/trade name is shown. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, it is unclear as to whether the claims are directed to the chemical names listed, or to the trademarks/trade names that are used to identify/describe the chemical names or zwitterionic agents. Accordingly, the identifications/descriptions are indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 14, 15, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Gobbers et al (J. Clin. Microbiol. 39(12): 4339-4343, 2001), as evidenced by Jany et al (FEBS Lett. 19(2): 139-144, 1986).

Gobbers taught a method of isolating hepatitis B virus genomic DNA. Viruses were treated with proteinase K and lysed in guanidinium thiocyanate. The nucleic acid was then bound to a solid support (silica particles). The DNA was isolated by elution from the silica particles. See last paragraph on page 4339, and paragraph bridging pages 4339 and 4340. Proteinase K is a zwitterionic compound at physiological pH as evidenced by Fig. 3 at page 142 of Jany which shows that proteinase K contains arginine, lysine, histidine, aspartate and glutamate residues. See e.g. positions 12, 26, 27, 46, and 57.

Claims 14-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Domanico et al (US Published Application 20040180445).

Domanico taught a method of isolating nucleic acids from bacterial, insect or mammalian cells by treating the cells with a lysis solution comprising guanidine hydrochloride, guanidine thiocyanate, N-decyl-N,N-dimethyl-3-ammonio-1-

propanesulfonate, and binding the nucleic acid to a solid matrix. See e.g. abstract, paragraph 30 on page 2, and Table 3 at page 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuipers et al (Ann. Rheum. Dis. 58: 103-108, 1999) in view of Domanico et al (US Published Application 20040180445).

Kuipers taught a method of isolating Chlamydia genomic DNA by treatment of synovial fluid with proteinase K and either an ionic or a nonionic detergent, addition of the cationic lipid CTAB, addition of a solid support, and elution of the DNA from the support. See abstract; Fig. 1 on page 104, e.g. methods 3b, 3c, 4b, and 4c; see also second and third full paragraphs of column 2 on page 104; and first two full paragraphs on page 105.

Kuipers did not teach a zwitterionic detergent or a chaotrope.

Domanico taught a method of isolating nucleic acids from bacterial, insect or mammalian cells by treating the cells with a lysis solution comprising guanidine hydrochloride, guanidine thiocyanate, N-decyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, and binding the nucleic acid to a solid matrix such as glass beads.

See e.g. abstract, paragraph 30 on page 2, Table 3 at page 8, and e.g. paragraphs 99-109 on page 9. Other zwitterionic detergents taught by Domanico include n-Tetradecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, n-Dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, Anzergent 3-14, Analytical Grade; Anzergent 3-8, Analytical Grade; Anzergent 3-10, Analytical Grade; Anzergent 3-12, Analytical Grade, respectively or zwittergent 3-8, zwittergent 3-10, zwittergent 3-12 and zwittergent 3-14, CHAPS, CHAPSO, Apo10 and Apo12. See paragraph 53 on page 5. Other chaotropic agents taught by Domanico include urea and sodium iodide. See paragraph 5.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use a zwitterionic detergent in the method of Kuipers because Domanico taught that non-ionic and zwitterionic detergents could be used as alternatives in DNA isolation procedures. See e.g. paragraph 9 on page 1. In fact, Domanico taught that the choice of detergents was a result-effective variable and explored the use of various different detergents and detergent mixtures, including a mixture of an ionic and a non-ionic detergent (see e.g. paragraphs 99 and 109 on page 9, and Table 5 on page 10. In view of the fact that use of non-ionic, anionic, cationic, and zwitterionic detergents in combination was known in the art at the time of the invention, and the fact that it was recognized that the identity of the detergents used influenced results, it would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the detergent content of a nucleic acid isolation mixture in order to maximize nucleic acid yield and purity. Similarly, because it was well known in the art at the time of the

invention that chaotropic compounds were useful in the isolation of nucleic acids from cells, e.g. Domanico taught the use of two chaotropes together in a single lysis buffer, it would have been obvious to one of ordinary skill in the art to use the chaotropes of Domanico in the method of Kuipers.

Pertinent to claims 21-24, it would have been obvious to one of ordinary skill in the art at the time of the invention to organize into a kit the elements of the invention of Kuipers as modified by Domanico because one of ordinary skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

Claims 21 and 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Domanico et al (US Published Application 20040180445).

Domanico taught a method of isolating nucleic acids from bacterial, insect or mammalian cells by treating the cells with a lysis solution comprising guanidine hydrochloride, guanidine thiocyanate, N-decyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, and binding the nucleic acid to a solid matrix such as glass beads. Domanico taught wash solutions comprising Tris buffer salts and alcohols, and alkaline elution buffers. See e.g. abstract; paragraph 30 on page 2; Table 3 at page 8; paragraphs 99-109 on page 9; and paragraphs 72 and 73 on pages 6 and 7. Other zwitterionic detergents taught by Domanico include n-Tetradecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, n-Octyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, n-Dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, Anzergent 3-14, Analytical

Grade; Anzergent 3-8, Analytical Grade; Anzergent 3-10, Analytical Grade; Anzergent 3-12, Analytical Grade, respectively or zwittergent 3-8, zwittergent 3-10, zwittergent 3-12 and zwittergent 3-14, CHAPS, CHAPSO, Apo10 and Apo12. See paragraph 53 on page 5. Other chaotropic agents taught by Domanico include urea and sodium iodide. See paragraph 5.

Domanico did not teach a kit comprising the various components of the method.

It would have been obvious to one of ordinary skill in the art at the time of the invention to organize the elements of the invention of Domanico into a kit because one of ordinary skill in the art appreciates that organizing experimental reagents prior to use is standard laboratory practice which reduces the frequency of errors.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 5-12, 14,15, 17-19, and 21-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over

claims 1-64 of U.S. Patent No. 6,762,027. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The claims of '027 are drawn to methods and kits for methods and kits for contacting whole tissue with a disrupting buffer comprising a protease and a cationic surfactant, substantially neutralizing the surfactant, and binding the nucleic acid to a solid phase. The specification teaches at column 10, lines 8-18 that "substantially neutralizing" embraces addition of one or more of chaotropes, nonionic surfactants, anionic surfactants, and zwitterionic surfactants. So, it would have been obvious through routine optimization to assess the activity of various combinations of chaotropes, nonionic surfactants, anionic surfactants, and zwitterionic surfactants, such as those required in instant claims 5-7, 11, 12, and 15. Claim 5 of '027 requires the use of the cationic surfactants of instant claims 10, 12, and 13. Claim 7 of '027 requires the use of a chaotrope selected from the group: NaBr, NaI, NaSCN, LiCl, LiBr, LiI, GuHCl, and GuSCN. Claim 25 of '027 requires isolating the bound nucleic acid, i.e. eluting it from the solid support. It is clear from the specification as a whole the claimed methods result in isolating genomic DNAs, see e.g. the brief descriptions of Figs. 13-30, at columns 3 and 4. Claim 15 of '027 requires the use of proteinases selected from proteinase K, proteinase, R, proteinase T, subtilisin DY, an alkaline serine protease from Streptomyces griseus, an alkaline serine protease from Bacillus lichenformis, dispase, subtilisin Calsberg, subtilopeptidase A, and thermolysin.

'027 does not teach a kit with wash or elution solutions, however, claims 25-40 require elution of the nucleic acid from the solid support. The portion of the specification

supporting these claims teaches that solid supports comprising DNA were washed in 90% ethanol and DNA was eluted in an alkaline solution buffered with Tris HCl and with a second solution of NaOH. See column 36. lines 31-41. It would have been obvious to one of ordinary skill in the art at the time of the invention to add the wash and elution solutions to the kits of the '027 patent simply because these solutions allow isolation of nucleic acids purified by the methods claimed in the '027 patent.

Claims 4, 13, 16, 20, and 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-64 of U.S. Patent No. 6,762,027 as applied to claims 1-3, 5-12, 14,15, 17-19, and 21-30 above, and further in view of Domanico et al (US Published Application 20040180445). Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The teachings of the '027 patent are discussed above. Although '027 teaches zwitterionic surfactants, it does not exemplify any.

Domanico taught a method of isolating nucleic acids from bacterial, insect or mammalian cells by treating the cells with a lysis solution comprising guanidine hydrochloride, guanidine thiocyanate, and the zwitterionic detergent N-decyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, and binding the nucleic acid to a solid matrix such as glass beads. See e.g. abstract, paragraph 30 on page 2, Table 3 at page 8, and e.g. paragraphs 99-109 on page 9. Other zwitterionic detergents taught by Domanico include n-Tetradecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, n-Octyl-

N,N-dimethyl-3-ammonio-1-propanesulfonate, n-Dodecyl-N,N-dimethyl-3-ammonio-1-propanesulfonate, Anzergent 3-14, Analytical Grade; Anzergent 3-8, Analytical Grade; Anzergent 3-10, Analytical Grade; Anzergent 3-12, Analytical Grade, respectively or zwittergent 3-8, zwittergent 3-10, zwittergent 3-12 and zwittergent 3-14, CHAPS, CHAPSO, Apo10 and Apo12. See paragraph 53 on page 5.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the zwitterionic detergents of Domanico in the methods and kits of '027 because the claims of '027 require substantial neutralization of a catrionic surfactant, and the specification of '027 teaches at column 10, lines 8-18 that "substantially neutralizing" embraces addition of one or more of chaotropes, nonionic surfactants, anionic surfactants, and zwitterionic surfactants. The zwitterionic surfactants of Domanico are used in a similar method, so it would have been clear to one of ordinary skill in the art at the time of the invention to use them in the methods and kits of the '027 patent. Regarding the tissue sources of instant claim 20, the "tissue" of the '027 claims includes biopsy materials and aspirates; in vitro cultured cells, including primary and secondary cells, transformed cell lines, and tissue and cellular explants; lymph; and body fluids such as urine, sputum, semen, secretions, eye washes and aspirates, lung washes and aspirates.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 571-273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Richard Schnizer, Ph.D.